

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
8 April 2004 (08.04.2004)

PCT

(10) International Publication Number
WO 2004/028265 A1

(51) International Patent Classification⁷: **A23G 3/30**

(21) International Application Number:
PCT/DK2002/000624

(22) International Filing Date:
24 September 2002 (24.09.2002)

(25) Filing Language: English

(26) Publication Language: English

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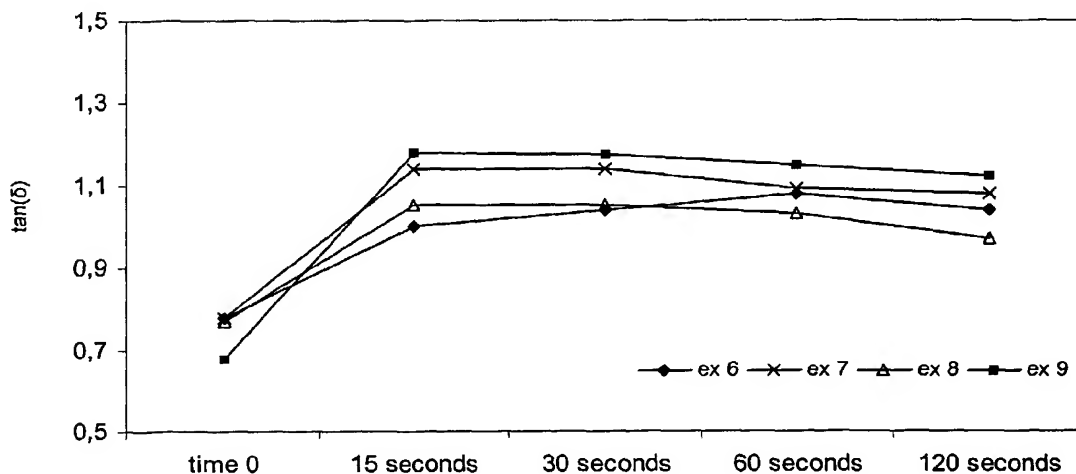
(81) Designated States (*national*): AE, AG, AL, AM, AT (utility model), AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ (utility model), CZ, DE (utility model), DE, DK (utility model), DK, DM, DZ, EC, EE (utility model), EE, ES, FI (utility model), FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK (utility model), SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: LOW MOISTURE CHEWING GUM



(57) Abstract: The invention relates to chewing gum comprising at least one biodegradable polymer and chewing gum ingredients, said chewing gum containing less than about 2.0 weight percent water of the chewing gum. According to the invention, a biodegradable chewing gum having low moisture has been provided in combination with an initial acceptable texture.

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LOW MOISTURE CHEWING GUM**Field of the invention**

The present invention relates to a chewing gum comprising at least one
5 biodegradable chewing gum polymer.

Background of the invention

A problem of the above described prior art biodegradable chewing gum is that the
10 chewing gum formulations applied typically degrades prior to the chewing of the
chewing gum.

It is the object of the invention to obtain a chewing gum in which the degradation of
the biodegradable polymer or polymers are minimized prior to the chewing of the
15 chewing gum.

Summary of the invention

According to the invention, it has been realized that even relatively small amounts of
water in the chewing gum containing biodegradable polymers affects the degradation
20 of the chewing gum even before chewing has occurred.

Therefore, a small amount of water or moisture within the chewing gum is highly
desired.

25 Moisture in chewing gum is typically provided by different water containing
chewing gum ingredients such as sweeteners. One type of sweetener is carbohydrate
syrops, such as conventional corn syrups or sugar alcohol syrups (including sorbitol
solutions and hydrogenated starch hydrolysate solutions) typically added to chewing
gum compositions to improve binding and softness characteristics in the gum.

30

A problem of a low moisture chewing gum is however generally, that a lower water content results in a less attractive texture of the chewing gum. Therefore, additional softeners typically need to be added.

- 5 This is however a problem, when dealing with biodegradable chewing gum due to the fact that chewing gum made on the basis of biodegradable polymer has turned out to be more vulnerable to softeners than chewing gum made on the basis of conventional polymers.
- 10 Surprisingly, it has been realized that chewing gum made on the basis of biodegradable polymers, most probably due to the hydrophilic nature of typical biodegradable polymers, exhibits a significantly faster gaining of softness during the initial chew compared to chewing gum made on the basis of conventional hydrophobic polymers.

15

- According to several experiments under different conditions, a chewing gum made on the basis of biodegradable polymers actually having an initial stiffness (the very first chew) greater than conventional chewing gum, actually increases in softness much faster than conventional chewing gum, thereby reaching the initial acceptable
- 20 texture before the conventional chewing gum. It has moreover been realized that this phenomena is also present when almost no moisture is present in the chewing gum as from the beginning.

- According to the invention, a biodegradable chewing gum having low moisture has
- 25 been provided. According to the invention, low moisture content has been obtained in combination with an initial acceptable texture.

In an embodiment of the invention the chewing gum contains less than about 2.0 weight percent water of the chewing gum

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In an embodiment of the invention the chewing gum contains from about 0.01 to about 2.0 weight percent water of the chewing gum.

According to an embodiment of the inventions, degradability tests have revealed that an acceptable chewing gum product having a certain stability with respect to degradation may be obtained when applying for moisture content as high as
5 approximately 1.0 weight percent of water indicating that the water content may be as high as 2.0 weight percent water of the chewing gum.

In an embodiment of the invention the chewing gum contains less than 1.0 weight percent water of the chewing gum
10

In an embodiment of the invention the chewing gum contains less than 0.75 weight percent water of the chewing gum

In an embodiment of the invention the chewing gum contains less than 0.2 weight percent water of the chewing gum
15

In an embodiment of the invention the chewing gum is substantially free of water containing sweeteners or softeners.

20 In an embodiment of the invention the chewing gum contains at least one low hygroscopic softener or sweetener.

In an embodiment of the invention the chewing gum contains at least one low hygroscopic softeners or chewing gum comprises powdered erythritol.
25

Aqueous syrups, such as corn syrup and hydrogenated corn syrup may be used, particularly if their moisture content is reduced. This can preferably be done by coevaporating the aqueous syrup with a plasticizer, such as glycerin or propylene glycol, to a moisture content of less than 10%. Preferred compositions include
30 hydrogenated starch hydrolyzate solids and glycerin. Such syrups and their methods of preparation are discussed in detail in U.S. Pat. No. 4,671,967, incorporated herein by reference.

In an embodiment of the invention the at least one biodegradable polymer is a polyester polymer obtained by the polymerization of one or more cyclic esters by ring-opening and where at least one of the cyclic esters are selected from the groups of glycolides, lactides, lactones, cyclic carbonates or mixtures thereof.

In an embodiment of the invention the at least one biodegradable polymer is a polyester copolymer obtained by the polymerization of two or more cyclic esters by ring-opening and where at least one of the cyclic esters are selected from the groups of glycolides, lactides, lactones, cyclic carbonates or mixtures thereof.

In an embodiment of the invention the rheological properties of the degradable polymer is controlled by adjusting the functional number of initiator.

In an embodiment of the invention the lactone monomers are chosen from the group of ϵ -caprolactone, δ -valerolactone, γ -butyrolactone, and β -propiolactone. It also includes ϵ -caprolactones, δ -valerolactones, γ -butyrolactones, or β -propiolactones that have been substituted with one or more alkyl or aryl substituents at any non-carbonyl carbon atoms along the ring, including compounds in which two substituents are contained on the same carbon atom and mixtures thereof.

In an embodiment of the invention the carbonate monomer is selected from the group of trimethylene carbonate, 5-alkyl-1,3-dioxan-2-one, 5,5-dialkyl-1,3-dioxan-2-one, or 5-alkyl-5-alkyloxycarbonyl-1,3-dioxan-2-one, ethylene carbonate, 3-ethyl-3-hydroxymethyl, propylene carbonate, trimethylolpropane monocarbonate, 4,6-dimethyl-1,3-propylene carbonate, 2,2-dimethyl trimethylene carbonate, and 1,3-dioxepan-2-one and mixtures thereof.

In an embodiment of the invention said chewing gum ingredients comprise flavoring agents.

In an embodiment of the invention said flavoring agents comprise natural and synthetic flavourings in the form of natural vegetable components, essential oils, essences, extracts, powders, including acids and other substances capable of affecting the taste profile

5

- In an embodiment of the invention said chewing gum comprises flavor in an amount of 0.01 to about 30 wt %, said percentage being based on the total weight of the chewing gum
- 10 In an embodiment of the invention said chewing gum comprises flavor in an amount of 0.2 to about 4 wt %, said percentage being based on the total weight of the chewing gum

In an embodiment of the invention said flavor comprises water soluble ingredients.

15

In an embodiment of the invention said water soluble flavor comprises acids.

According to the invention, a surprising initial release of acids has been obtained.

20 In an embodiment of the invention said flavor comprising water insoluble ingredients.

In an embodiment of the invention, said chewing gum ingredients comprising sweeteners.

25

In an embodiment of the invention said sweetener comprises bulk sweeteners

In an embodiment of the invention the chewing gum comprises bulk sweeteners in an amount of about 5 to about 95% by weight of the chewing gum, more typically about

30 20 to about 80% by weight of the chewing gum.

In an embodiment of the invention the sweetener comprises high intensity sweeteners

In an embodiment of the invention the high intensity sweeteners comprises sucralose, aspartame, salts of acesulfame, alitame, saccharin and its salts, cyclamic acid and its salts, glycyrrhizin, dihydrochalcones, thaumatin, monellin, sterioside, alone or in
5 combination

In an embodiment of the invention wherein the chewing gum comprises high intensity sweeteners in an amount of about 0 to about 1% by weight of the chewing gum, more typically about 0.05 to about 0.5 % by weight of the chewing gum.

10

In an embodiment of the invention, the chewing gum comprises at least one softener.

In an embodiment of the invention, the at least one softener comprises tallow, hydrogenated tallow, hydrogenated and partially hydrogenated vegetable oils, cocoa
15 butter, glycerol monostearate, glycerol triacetate, lecithin, mono-, di- and triglycerides, acetylated monoglycerides, fatty acids - such as stearic, palmitic, oleic and linoleic acids mixtures thereof.

In an embodiment of the invention the chewing gum comprises softeners in an
20 amount of about 0 to about 18% by weight of the chewing gum, more typically about 0 to about 12 % by weight of the chewing gum.

In an embodiment of the invention, the chewing gum ingredients comprise active ingredients.

25

In an embodiment of the invention, said active ingredients are selected from the group of: Acetaminophen, Acetylsalicylsyre Buprenorphine Bromhexin Celcoxib Codeine, Diphenhydramin, Diclofenac, Etoricoxib, Ibuprofen, Indometacin, Ketoprofen, Lumiracoxib, Morphine, Naproxen, Oxycodon, Parecoxib, Piroxicam,
30 Pseudoefedrin, Rofecoxib, Tenoxicam, Tramadol, Valdecocix, Calciumcarbonat, Magaldrate, Disulfiram, Bupropion, Nicotine, Azithromycin, Clarithromycin, Clotrimazole, Erythromycin, Tetracycline, Granisetron, Ondansetron, Prometazin,

- Tropisetron, Brompheniramine, Ceterizin, Ieco-Ceterizin, Chlorcyclizine, Chlorpheniramin, Chlorpheniramin, Difenhydramine, Doxylamine, Fenofenadin, Guaifenesin, Loratidin, des-Loratidin, Phenyltoloxamine, Promethazin, Pyridamine, Terfenadin, Troxerutin, Methyldopa, Methylphenidate, Benzalcon. Chloride, Benzeth. Chloride, Cetylpyrid. Chloride, Chlorhexidine, Ecabet-sodium, Haloperidol, Allopurinol, Colchicine, Theophylline, Propanolol, Prednisolone, Prednisone, Fluoride, Urea, Miconazole, Actot, Glibenclamide, Glipizide, Metformin, Miglitol, Repaglinide, Rosiglitazone, Apomorphin, Cialis, Sildenafil, Vardenafil, Diphenoxylate, Simethicone, Cimetidine, Famotidine, Ranitidine, Ratinidine, cetirizin, Loratadine, Aspirin, Benzocaine, Dextrometorphan, Ephedrine, Phenylpropanolamine, Pseudoephedrine, Cisapride, Domperidone, Metoclopramide, Acyclovir, Dioctylsulfosucc., Phenolphthalein, Almotriptan, Eletriptan, Ergotamine, Migea, Naratriptan, Rizatriptan, Sumatriptan, Zolmitriptan, Aluminium salts, Calcium salts, Ferro salts, Silver salts, Zinc-salte, Amphotericin B, Chlorhexidine, Miconazole, Triamcinolonacetone, Melatonin, Phenobarbital, Caffeine, Benzodiazepine, Hydroxyzine, Meprobamate, Phenothiazine, Buclizine, Brometazine, Cinnarizine, Cyclizine, Difenhydramine, Dimenhydrinate, Buflomedil, Amphetamine, Caffeine, Ephedrine, Orlistat, Phenylephedrine, Phenylpropanolamine, Pseudoephedrine, Sibutramine, Ketoconazole, Nitroglycerin, Nystatin, Progesterone, Testosterone, Vitamin B12, Vitamin C, Vitamin A, Vitamin D, Vitamin E, Pilocarpin, Aluminiumaminoacetate, Cimetidine, Esomeprazole, Famotidine, Lansoprazole, Magnesiumoxide, Nizatide and or Ratinidine or derivatives and mixtures thereof.

- 25 In an embodiment of the invention, the chewing gum is substantially free of non-biodegradable polymers

- In an embodiment of the invention the at least two or more cyclic esters are selected from the groups of glycolides, lactides, lactones, cyclic carbonates or mixtures thereof.

In an embodiment of the invention the lactone monomers are chosen from the group of ϵ -caprolactone, δ -valerolactone, γ -butyrolactone, and β -propiolactone. It also includes ϵ -caprolactones, δ -valerolactones, γ -butyrolactones, or β -propiolactones that have been substituted with one or more alkyl or aryl substituents at any non-carbonyl carbon atoms along the ring, including compounds in which two substituents are
5 contained on the same carbon atom.

In an embodiment of the invention the carbonate monomer is selected from the group of trimethylene carbonate, 5-alkyl-1,3-dioxan-2-one, 5,5-dialkyl-1,3-dioxan-2-one, or 5-alkyl-5-alkyloxycarbonyl-1,3-dioxan-2-one, ethylene carbonate, 3-ethyl-3-hydroxymethyl, propylene carbonate, trimethylolpropane monocarbonate, 4,6dimethyl-1,3-propylene carbonate, 2,2-dimethyl trimethylene carbonate, and 1,3-dioxepan-2-one and mixtures thereof.
10

15 In an embodiment of the invention the cyclic ester polymers and their copolymers resulting from the polymerization of cyclic ester monomers include, but are not limited to : poly (L-lactide) ; poly (D-lactide) ; poly (D, L-lactide) ; poly (mesolactide) ; poly (glycolide) ; poly (trimethylenecarbonate) ; poly (epsilon-caprolactone) ; poly (L-lactide-co-D, L-lactide) ; poly (L-lactide-co-meso-lactide) ; poly (L-lactide-co-glycolide) ; poly (L-lactide-co-trimethylenecarbonate) ; poly (L-lactide-co-epsilon-caprolactone) ; poly (D, L-lactide-co-meso-lactide) ; poly (D, L-lactide-co-glycolide) ; poly (D, L-lactide-co-trimethylenecarbonate) ; poly (D, L-lactide-co-epsilon-caprolactone) ; poly (meso-lactide-co-glycolide) ; poly (meso-lactide-co-trimethylenecarbonate) ; poly (meso-lactide-co-epsilon-caprolactone) ; poly (glycolide-cotrimethylenecarbonate) ; poly (glycolide-co-epsilon-caprolactone).
20
25

In an embodiment of the invention the chewing gum comprises filler.
30

A chewing gum base formulation may, if desired, include one or more fillers/texturisers including as examples, magnesium and calcium carbonate, sodium

sulphate, ground limestone, silicate compounds such as magnesium and aluminium silicate, kaolin and clay, aluminium oxide, silicium oxide, talc, titanium oxide, mono-, di- and tri-calcium phosphates, cellulose polymers, such as wood, and combinations thereof.

5

In an embodiment of the invention the chewing gum comprises filler in an amount of about 0 to about 50% by weight of the chewing gum, more typically about 10 to about 40 % by weight of the chewing gum.

- 10 In an embodiment of the invention the chewing gum comprises at least one coloring agent.

- According to an embodiment of the invention, the chewing gum may comprise color agents and whiteners such as FD&C-type dyes and lakes, fruit and vegetable
15 extracts, titanium dioxide and combinations thereof. Further useful chewing gum base components include antioxidants, e.g. butylated hydroxytoluene (BHT), butyl hydroxyanisol (BHA), propylgallate and tocopherols, and preservatives.

- In an embodiment of the invention the chewing gum is coated with an outer coating.
20

In an embodiment of the invention the outer coating is a hard coating.

- In an embodiment of the invention the hard coating is a coating selected from the group consisting of a sugar coating and a sugarless coating and a combination
25 thereof.

- In an embodiment of the invention the hard coating comprises 50 to 100% by weight of a polyol selected from the group consisting of sorbitol, maltitol, mannitol, xylitol, erythritol, lactitol and isomalt.

30

In an embodiment of the invention the outer coating is an edible film comprising at least one component selected from the group consisting of an edible film-forming agent and a wax.

- 5 In an embodiment of the invention the film-forming agent is selected from the group consisting of a cellulose derivative, a modified starch, a dextrin, gelatine, shellac, gum arabic, zein, a vegetable gum, a synthetic polymer and any combination thereof.

- 10 In an embodiment of the invention the outer coating comprises at least one additive component selected from the group consisting of a binding agent, a moisture absorbing component, a film forming agent, a dispersing agent, an antisticking component, a bulking agent, a flavouring agent, a colouring agent, a pharmaceutically or cosmetically active component, a lipid component, a wax component, a sugar, an acid and an agent capable of accelerating the after-chewing
15 degradation of the degradable polymer.

In an embodiment of the invention the outer coating is a soft coating.

- 20 In an embodiment of the invention the soft coating comprises a sugar free coating agent.

In an embodiment of the invention the chewing gum comprises conventional chewing gum polymers or resins.

- 25 In an embodiment of the invention the at least one biodegradable polymer comprises at least 5% of the chewing gum polymers.

- 30 In an embodiment of the invention all the biodegradable polymers comprised in the chewing gum comprises at least 25%, preferably at least 50% of the chewing gum polymers.

In an embodiment of the invention the biodegradable polymers comprised in the chewing gum comprises at least 80%, preferably at least 90% of the chewing gum polymers.

- 5 In an embodiment of the invention the chewing gum comprises said at least one biodegradable polyester copolymer forming a plasticizer of the chewing gum and at least one non-biodegradable conventional elastomer

According to the invention, a biodegradable polymer according to the invention may
10 form a substitute of a conventional natural or synthetic resin.

In an embodiment of the invention the chewing gum comprises the at least one biodegradable polyester copolymer forming an elastomer of the chewing gum and at least one non-biodegradable conventional natural or synthetic
15 resin.

According to the invention, a biodegradable polymer according to the invention may form a substitute of a conventional low or high molecular weight elastomer.

- 20 In an embodiment of the invention said chewing gum comprises

at least one biodegradable elastomer in the amount of about 0.5 to about 70% wt of the chewing gum,

- 25 at least one biodegradable plasticizer in the amount of about 0.5 to about 70% wt of the chewing gum and

at least one chewing gum ingredient chosen from the groups of softeners, sweeteners, flavoring agents, active ingredients and fillers in the amount of about 2 to about 80%
30 wt of the chewing gum.

In an embodiment of the invention edible polyesters may be applied as a degradable chewing gum polymer.

Edible polyesters are obtained by esterification of at least one alcohol and one acid.

5

The edible polyester is produced by condensation polymerization reaction of at least one alcohol chosen from the group of trihydroxyl alcohol and dihydroxyl alcohol, and at least one acid chosen from the group consisting of dicarboxylic acid and tricarboxylic acid.

10

It is possible to use edible or food grade materials. Because the starting acids and alcohols are food grade materials the resultant polymers is edible.

Alcohols: Glycerol, propylene glycol, 1,3 butylene diol

15

Acids: Citric acid, fumaric acid, adipic acid, malic acid, succinic acid, suberic acid, sebacic acid, dodecanedioic acid, glucaric acid, glutamic acid, glutaric, azelaic acid, tartaric acid

20 Edible polyesters can replace both elastomers and elastomer plasticizers and form 1-80% of the gum base.

The drawing

25 The invention will now be described with reference to the drawings of which fig. 1 and 2 illustrate the texture of chewing gum according to the inveniton.

Detailed description

30 In the present context the terms environmentally or biologically degradable polymer compounds refers to chewing gum base components which, after dumping the chewing gum, is capable of undergoing a physical, chemical and/or biological degradation whereby the dumped chewing gum waste becomes more readily

removable from the site of dumping or is eventually disintegrated to lumps or particles which are no longer recognisable as being chewing gum remnants. The degradation or disintegration of such degradable polymers can be effected or induced by physical factors such as temperature, light, moisture, by chemical factors such as hydrolysis caused by a change in pH or by the action of enzymes capable of degrading the polymers. In other useful embodiments all of the polymer components of the gum base are environmentally degradable or biodegradable polymers.

Preferably, the ultimate degradation products are carbon dioxide, methane and water.

According to a preferred definition of biodegradability according to the invention biodegradability is a property of certain organic molecules whereby, when exposed to the natural environment or placed within a living organism, they react through an enzymatic or microbial process, often in combination with a pure chemical process such as hydrolysis, to form simpler compounds, and ultimately, carbon dioxide, nitrogen oxides, and water.

Accordingly, suitable examples of additional environmentally or biologically degradable chewing gum base polymers which can be applied in accordance with the gum base of the present invention include degradable polyesters, polycarbonates, polyester amides, polypeptides, homopolymers of amino acids such as polylysine, and proteins including derivatives hereof such as e.g. protein hydrolysates including a zein hydrolysate. Particularly useful compounds of this type include polyester polymers obtained by the polymerisation of one or more cyclic esters such as lactide, glycolide, trimethylene carbonate, δ -valerolactone, β -propiolactone and ϵ -caprolactone. Such degradable polymers may be homopolymers or copolymers, including block-polymers.

Unless otherwise indicated, as used herein, the term "molecular weight" means number average molecular weight (M_n).

EXAMPLE 1

Preparation of resin

- A resin sample was produced using a cylindrical glass, jacketed 10 L pilot reactor equipped with glass stir shaft and Teflon stir blades and bottom outlet. Heating of the reactor contents was accomplished by circulation of silicone oil, thermostated to 130°C, through the outer jacket. D,L-lactide (4.877 kg, 33.84 mol) was charged to the reactor and melted by heating to 140 °C for 6 h. After the D,L-lactide was completely molten, the temperature was reduced to 130 °C, and stannous octoate (1.79 g, 4.42×10^{-3} mol), 1,2-propylene glycol (79.87 g, 1.050 mol), and ϵ -caprolactone (290.76 g, 2.547 mol) were charged to the reactor. After the mixture became homogeneous, stirring was continued for 24 h at 130°C. At the end of this time, the bottom outlet was opened, and molten polymer was allowed to drain into a Teflon-lined paint can.
- Characterization of the product indicated $M_n = 5,700$ g/mol and $M_w = 7,100$ g/mol (gel permeation chromatography with online MALLS detector) and $T_g = 30.7$ °C (DSC, heating rate 10°C/min).

EXAMPLE 2

Preparation of LMWE elastomer

- A LMWE sample was synthesized within a dry N₂ glove box, as follows. Into a 500 mL resin kettle equipped with overhead mechanical stirrer, 0.40 g 1,2-propane diol (1.82 mL of a 22.0 % (w/v) solution in MeCl₂), and 0.094 g Sn(Oct)₂ (2.2 mL of a 4.27 % (w/v) solution of in MeCl₂) were charged under dry N₂ gas purge. The
- 5 MeCl₂ was allowed to evaporate under the N₂ purge for 15 min. Then ε-caprolactone (170 g, 1.49 mol), TMC (76g, 0.74 mol), and δ-valerolactone (74 g, 0.74 mol) were added. The resin kettle was submerged in a 130 °C constant-temperature oil bath and stirred for 14 h. Subsequently the kettle was removed from the oil bath and allowed to cool to room temperature.
- 10 Characterization of the product indicated M_n = 57,960 g/mol and M_w = 85,910 g/mol (gel permeation chromatography with online MALLS detector) and T_g = - 59.8°C (DSC, heating rate 10°C/min).

15 EXAMPLE 3

Preparation of HMWE

- A HMWE sample was synthesized in a dry N₂ glove box, as follows. Into a 500 mL resin kettle equipped with overhead mechanical stirrer was charged 0.037 g Sn(Oct)₂ (2.4 ml of a 1.54% (w/v) solution in methylene chloride) under dry N₂ gas purge. The methylene chloride was allowed to evaporate under the N₂ purge for 15 min. Then, pentaerythritol (0.068 g, 4.99 x 10⁻⁴ mol), ε-caprolactone (68.0g, 0.596 mol), TMC (7.0 g, 0.069 mol), and δ-valerolactone (33.0 g, 0.33 mol) were added. The
- 25 resin kettle was then submerged in a 130 °C constant-temperature oil bath and stirred for about 2 - 2.5 h, at which time the mass solidified and could no longer be stirred. The reacting mass was then maintained at 130 °C for an additional 11.5 – 12 h for a total reaction time of 14 h. Subsequently the kettle was removed from the oil bath and allowed to cool to room temperature..
- 30 Characterization of the product indicated M_n = 113,900 g/mol and M_w = 369,950 g/mol (gel permeation chromatography with online MALLS detector).

EXAMPLE 4**Preparation of gum bases**

5

All the gum bases are prepared with following basic formulation:

	Ingredients	Percent by weight
10	Elastomer HMWE	20
	Elastomer LMWE	40
	Resin	40

The gum bases are prepared as follows:

15 HMWE elastomer is added to a mixing kettle provided with mixing means like e.g. horizontally placed Z-shaped arms. The kettle had been preheated for 15 minutes to a temperature of about 60-80 °C. The rubber is broken into small pieces and softened with mechanical action on the kettle.

The resin is slowly added to the elastomer until the mixture becomes homogeneous.

20 The remaining resin is then added to the kettle and mixed for 10-20 minutes. The LMWE elastomer is added and mixed for 20-40 minutes until the whole mixture becomes homogeneous.

The mixture is then discharged into the pan and allowed to cool to room temperature from the discharged temperature of 60-80 °C, or the gumbase mixture is used
25 directly for chewing gum by adding all chewing gum components in an appropriate order under continuous mixing.

EXAMPLE 5

30

Preparation of Chewing gum

All chewing gum formulations are prepared with the following basic formulation

Ingredients	Percent by weight	
	(Mint formulation with maltitol syrup)	(Mint formulation without maltitol syrup)
5		
Gum base	40	40
Sorbitol	48.6	51,6
Maltitol syrup	3	-
10		
Peppermint oil	1.5	5
Menthol crystals	0.5	0.5
Strawberry	-	-
Aspartame	0.2	0.2
Acesulfame	0.2	0.2
15		
Xylitol	6	6
Approx. amount of water:	1.5%	0.5%

- 20 The water is primary added via the maltitol syrup, but also contributions from the bulk sweetener are present.

The chewing gum products are prepared as follows:

- 25 The gum base is added to a mixing kettle provided with mixing means like e.g. horizontally placed Z-shaped arms. The kettle had been preheated for 15 minutes to temperatures of about 60-80 °C. Or the mixing step is continued directly from the gum base preparation i.e. in a one step operation. The mixing process is preformed at a temperatures between 60-80 °C.

30

One third portion of the sorbitol is added together with the gum base and mixed for 1-2 minutes. Another one third portion of the sorbitol and lycasin are then added to

the kettle and mixed for 2 minutes. The remaining one third portion of sorbitol, peppermint and menthol are added and mixed for 2 minutes. Then aspartame and acesulfame are added to the kettle and mixed for 3 minutes. Xylitol is added and mixed for 3 minutes. The resulting gum mixture is then discharged and e.g.

- 5 transferred to a pan at temperature of 40-48 °C. The gum is then rolled and scored into cores, sticks, balls, cubes, and nay other desired shape, optionally followed by coating and polishing processes prior to packaging.

10 EXAMPLE 6-9

Rheological texture profile of conventional and biodegradable chewing gum containing flavor.

Ex	Gum base	Polymer 1	Polymer 2	Polymer 3	Chewing gum
6	Standard conventional gum base	Butyl rubber Mn =117.000	PIB Mn =30.000	PVA Mn =5000	Mint
7	Gum base based only on example 2	Butyl rubber Mn =117.000	Elastomer according to example 2	PVA Mn =5000	Mint
8	Gum base based only on example 1	Butyl rubber Mn =117.000	Polyisobutylen e Mn =30.000	Polymer according to example 1	Mint
9	Gum base based only on example 1-2	Butyl rubber Mn =117.000	Elastomer according to example 2	Polymer according to example 1	Mint

15

Mint refers to the chewing gum formulation of example 5 with maltitol syrup.

Figure 1 illustrates rheological chewing profiles of the chewing gum corresponding to example 6-9. The gum centres were chewed in a chewing machine (CF Jansson). The chewing frequency was set to 1 Hz, a pH buffer was used as saliva and the temperature was set at 37 °C. The chewing time was set to 15 sec, 30 sec, 60 sec and 120 sec. After chewing, the chewed cud was measured on a rheometer, type AR1000 from TA Instruments in a frequency scan. The results from these measurements can be seen on Fig 1 and 2 wherein the storage modulus (G') and $\tan(\delta)$ versus chewing time is depicted illustrating the texture changes during chewing.

10

From figure 1 it can be seen that the biodegradable chewing gums ex. 7-9 are softening faster than the chewing gum ex. 6 being 100% conventional seen as an increased slope in $\tan \delta$ i.e. a faster development of viscous flow. The figure also illustrates that ex. 9 containing 80% of biodegradable polymer is softening faster than the two other chewing gums containing only 40% biodegradable polymer. This figure also states that textures of chewing gum containing biodegradable polymers are comparable to the texture of a conventional chewing gum. In summery, the more biodegradable polymer in the chewing gum the faster it softens.

20

EXAMPLE 10-11

Rheological texture profile of conventional and biodegradable chewing gum with and without maltitol syrup in the formulation.

25

Ex	Gum base	Polymer 1	Polymer 2	Polymer 3	Chewing gum
10	100 % biodegradabl e gum base	Elastomer according to example 3	Elastomer according to example 2	Polymer according to example 1	Mint (without maltitol syrup)
11	100 % biodegradabl	Elastomer according to	Elastomer according to	Polymer according to	Mint (with maltitol

	e gum base	example 3	example 2	example 1	syrup)
--	------------	-----------	-----------	-----------	--------

Mint refers to the chewing gum formulation of example 5.

Figure 2 show the effect on texture when leaving the maltitol syrup out of the
 5 formulation as ex. 10 being without maltitol syrup is having a lower $\tan \delta$ i.e. a
 higher stiffness. The texture of ex. 10 approaches ex. 11 fast reaching ex. 10 after
 approx. 20 seconds of chewing.

In summery, the loss of softness in the initial chew as seen in the chewing gum
 without maltitol syrup is fast compensated by the fast uptake of saliva in the chewing
 10 gum as a result of the hydrophilic nature of the biodegradable polymers used.

EXAMPLE 12

15 **Hardness**

The hardness of the two examples 10 and 11 were measured in order to determine
 instant hardness i.e. a measure of the chewing resistance in the first few chews in the
 chewing gums. The hardness of the test samples were tested by an compression load
 test using a TA-XT2i TEXTURE analyser from Stable Micro Systems with a 4 mm
 20 DIA CYLINDER STAINLESS at a speed of 0.4 mm/s using a test distance of 3.5
 mm into the chewing gum body.

The test result (N) of this experiment is shown in the below Table 1

Example	Hardness (N)	S.D
10	49.29	1.46
11	33.27	0.69

25

Table 1: Hardness of biodegradable chewing gum with and without maltitol syrup-

As can be seen from the above Table 1, the chewing gum samples containing maltitol syrup are softer than the chewing gum without the maltitol syrup in accordance with the result in example 10-11.

5

EXAMPLE 13

Degradation of biodegradable chewing gum with and without maltitol syrup in the formulation.

10

A panel evaluated the two samples over a period of 4 months every one month. The following rating was used:

Rating	Description
1	Very poor
2	Poor
3	Acceptable
4	Good
5	Very good

15 Table 2: Ratings

Time	Example 10		Example 11	
	Texture	Taste	Texture	Taste
0 month	4	5	4	5
1 month	4	5	4	5
2 month	4	5	3	4
3 month	4	4	3	3
4 month	4	4	1-2	2

Table 3: Evaluation of degradation

Experiments by evaluating the texture and the taste as a function of time have shown that the ex. 10 - without maltitol syrup - has significant improved taste and texture. Hence, it is thereby indicated that low water content in the chewing gum formulations improves the biodegradable chewing gum resulting in a prolonged shelf

5 life.

The degradation rate according to example 11 is regarded as acceptable for certain purposes.

Patent Claims

1. Chewing gum comprising at least one biodegradable polymer and chewing gum ingredients,
- 5 said chewing gum ingredients being chosen from the groups of softeners, sweeteners, flavoring agents, active ingredients, fillers, mixtures thereof and
- 10 said chewing gum containing less than about 2.0 weight percent water of the chewing gum
2. Chewing gum according to claim 1, wherein said chewing gum containing from about 0.01 to about 2.0 weight percent water of the chewing gum
- 15 3. Chewing gum according to claim 1 or 2, wherein said chewing gum containing less than 1.0 weight percent water of the chewing gum
4. Chewing gum according to claim any of the claims 1-3, wherein said chewing gum containing less than 0.75 weight percent water of the chewing gum
- 20 5. Chewing gum according to claim any of the claims 1-4, wherein said chewing gum containing less than 0.2 weight percent water of the chewing gum
6. Chewing gum according to claim any of the claims 1-5,
- 25 wherein the at least one biodegradable polymer is a polyester polymer obtained by the polymerization of one or more cyclic esters by ring-opening and where at least one of the cyclic esters are selected from the groups of glycolides, lactides, lactones, cyclic carbonates or mixtures thereof.
- 30 7. Chewing gum according to claim any of the claims 1-6, wherein the at least one biodegradable polymer is a polyester copolymer obtained by the polymerization of two or more cyclic esters by ring-opening and where at least

one of the cyclic esters are selected from the groups of glycolides, lactides, lactones, cyclic carbonates or mixtures thereof.

8. Chewing gum according to claim any of the claims 1-7,
5 wherein the rheological properties of the degradable polymer is controlled by adjusting the functional number of initiator.

9. Chewing gum according to claim any of the claims 1-8,
wherein the lactone monomers are chosen from the group of ϵ -caprolactone, δ -
10 valerolactone, γ -butyrolactone, and β -propiolactone. It also includes ϵ -caprolactones, δ -valerolactones, γ -butyrolactones, or β -propiolactones that have been substituted with one or more alkyl or aryl substituents at any non-carbonyl carbon atoms along the ring, including compounds in which two substituents are contained on the same carbon atom and mixtures thereof.

15
10. Chewing gum according to claim any of the claims 1-9,
wherein the carbonate monomer is selected from the group of trimethylene carbonate, 5-alkyl-1,3-dioxan-2-one, 5,5-dialkyl-1,3-dioxan-2-one, or 5-alkyl-5-alkyloxycarbonyl-1,3-dioxan-2-one, ethylene carbonate, 3-ethyl-3-hydroxymethyl,
20 propylene carbonate, trimethylolpropane monocarbonate, 4, 6dimethyl-1, 3-propylene carbonate, 2, 2-dimethyl trimethylene carbonate, and 1, 3-dioxepan-2-one and mixtures thereof.

11. Chewing gum according to claim any of the claims 1-10,
25 wherein the chewing gum is substantially free of water containing sweeteners or softeners.

12. Chewing gum according to claim any of the claims 1-11,
wherein the chewing gum comprises at least one low hygroscopic softener or
30 sweetener.

13. Chewing gum according to claim any of the claims 1-12,

wherein the at least one low hygroscopic softeners or chewing gum comprises powdered erithritol.

14. Chewing gum according to any of claims 1- 13, wherein
5 said chewing gum ingredients comprise flavoring agents.

15. Chewing gum according to any of claims 1- 14, wherein
said flavoring agents comprises natural and synthetic flavorings in the form of
natural vegetable components, essential oils, essences, extracts, powders, including
10 acids and other substances capable of affecting the taste profile

16. Chewing gum according to any of claims 1-15, wherein
said chewing gum comprises flavor in an amount of 0.01 to about 30 wt %, said
percentage being based on the total weight of the chewing gum
15

17. Chewing gum according to any of claims 1-16, wherein
said chewing gum comprises flavor in an amount of 0.2 to about 4 wt %, said
percentage being based on the total weight of the chewing gum

20 18. Chewing gum according to any of claims 1- 17, wherein
said flavor comprises water soluble ingredients.

19. Chewing gum according to any of claims 1-18, wherein
said water soluble flavor comprises acids.
25

20. Chewing gum according to any of claims 1-19, wherein
said flavor comprises water insoluble ingredients.

21. Chewing gum according to any of claims 1- 20, wherein
30 said chewing gum ingredients comprising sweeteners.

22. Chewing gum according to any of claims 1-21,

wherein said sweetener comprises bulk sweeteners

23. Chewing gum according to any of claims 1-22,
wherein the chewing gum comprises bulk sweeteners in the amount of about 5 to
5 about 95% by weight of the chewing gum, more typically about 20 to about 80% by
weight of the chewing gum.

24. Chewing gum according to any of claims 1-23, wherein said sweetener comprises
high intensity sweeteners

10

25. Chewing gum according to any of claims 1-24, wherein the high intensity
sweeteners comprises sucralose, aspartame, salts of acesulfame, alitame, saccharin
and its salts, cyclamic acid and its salts, glycyrrhizin, dihydrochalcones, thaumatin,
monellin, sterioside, alone or in combination

15

26. Chewing gum according to any of claims 1-25,
wherein the chewing gum comprises high intensity sweeteners in an amount of about
0 to about 1% by weight of the chewing gum, more typically about 0.05 to about 0.5
% by weight of the chewing gum.

20

27. Chewing gum according to any of claims 1- 26,
wherein the chewing gum comprises at least one softener.

28. Chewing gum according to any of claims 1- 27,
25 wherein the at least one softener comprises tallow, hydrogenated tallow,
hydrogenated and partially hydrogenated vegetable oils, cocoa butter, glycerol
monostearate, glycerol triacetate, lecithin, mono-, di- and triglycerides, acetylated
monoglycerides, fatty acids - such as stearic, palmitic, oleic and linoleic acids,
waxes, PGE and mixtures thereof.

30

29. Chewing gum according to any of claims 1- 28,

wherein the chewing gum comprises softeners in the amount of about 0 to about 18% by weight of the chewing gum, more typically about 0 to about 12 % by weight of the chewing gum.

- 5 30. Chewing gum according to any of claims 1- 29, wherein said chewing gum ingredients comprise active ingredients.
31. Chewing gum according to any of claims 1- 30, said active ingredients being selected from the group of: Acetaminophen, Acetylsalicylsyre Buprenorphine
- 10 Bromhexin Celcoxib Codeine, Diphenhydramin, Diclofenac, Etoricoxib, Ibuprofen, Indometacin, Ketoprofen, Lumiracoxib, Morphine, Naproxen, Oxycodon, Parecoxib, Piroxicam, Pseudoefedrin, Rofecoxib, Tenoxicam, Tramadol, Valdecocib, Calciumcarbonat, Magaldrate, Disulfiram, Bupropion, Nicotine, Azithromycin, Clarithromycin, Clotrimazole, Erythromycin, Tetracycline, Granisetron,
- 15 Ondansetron, Prometazin, Tropisetron, Brompheniramine, Ceterizin, Ieco-Ceterizin, Chlorcyclizine, Chlorpheniramin, Chlorpheniramin, Difenhydramine, Doxylamine, Fenofenadin, Guaifenesin, Loratidin, des-Loratidin, Phenyltoloxamine, Promethazin, Pyridamine, Terfenadin, Troxerutin, Methyldopa, Methylphenidate, Benzalcon. Chloride, Benzeth. Chloride, Cetylpyrid. Chloride, Chlorhexidine, Ecabet-sodium,
- 20 Haloperidol, Allopurinol, Colchicine, Theophylline, Propanolol, Prednisolone, Prednisone, Fluoride, Urea, Miconazole, Actot, Glibenclamide, Glipizide, Metformin, Miglitol, Repaglinide, Rosiglitazone, Apomorfin, Cialis, Sildenafil, Vardenafil, Diphenoxylate, Simethicone, Cimetidine, Famotidine, Ranitidine, Ratinidine, cetirizin, Loratadine, Aspirin, Benzocaine, Dextrometorphan, Ephedrine,
- 25 Phenylpropanolamine, Pseudoephedrine, Cisapride, Domperidone, Metoclopramide, Acyclovir, Dioctylsulfosucc., Phenolphthalein, Almotriptan, Eletriptan, Ergotamine, Migea, Naratriptan, Rizatriptan, Sumatriptan, Zolmitriptan, Aluminium salts, Calcium salts, Ferro salts, Silver salts, Zinc-salte, Amphotericin B, Chlorhexidine, Miconazole, Triamcinolonacetoneid, Melatonine, Phenobarbitol, Caffeine,
- 30 Benzodiazepiner, Hydroxyzine, Meprobamate, Phenothiazine, Buclizine, Brometazine, Cinnarizine, Cyclizine, Difenhydramine, Dimenhydrinate, Buflomedil, Amphetamine, Caffeine, Ephedrine, Orlistat, Phenylephedrine, Phenylpropanolamin,

Pseudoephedrine, Sibutramin, Ketoconazole, Nitroglycerin, Nystatin, Progesterone, Testosterone, Vitamin B12, Vitamin C, Vitamin A, Vitamin D, Vitamin E, Pilocarpin, Aluminiumaminoacetat, Cimetidine, Esomeprazole, Famotidine, Lansoprazole, Magnesiumoxide, Nizatide and/or Ratinidine or derivates and
5 mixtures thereof.

32. Chewing gum according to any of claims 1-31, wherein the chewing gum is substantially free of non-biodegradable polymers

10 33. Chewing gum according to any of claims 1-32, wherein the at least two or more cyclic esters are selected from the groups of glycolides, lactides, lactones, cyclic carbonates or mixtures thereof.

34. Chewing gum according to any of claims 1-33, wherein lactone monomers are
15 chosen from the group of ϵ -caprolactone, δ -valerolactone, γ -butyrolactone, and β -propiolactone. It also includes ϵ -caprolactones, δ -valerolactones, γ -butyrolactones, or β -propiolactones that have been substituted with one or more alkyl or aryl substituents at any non-carbonyl carbon atoms along the ring, including compounds in which two substituents are contained on the same carbon atom.

20

35. Chewing gum according to any of claims 1-34,
wherein the carbonate monomer is selected from the group of trimethylene carbonate, 5-alkyl-1,3-dioxan-2-one, 5,5-dialkyl-1,3-dioxan-2-one, or 5-alkyl-5-alkyloxycarbonyl-1,3-dioxan-2-one, ethylene carbonate, 3-ethyl-3-hydroxymethyl,
25 propylene carbonate, trimethylolpropane monocarbonate, 4, 6dimethyl-1, 3-propylene carbonate, 2, 2-dimethyl trimethylene carbonate, and 1, 3-dioxepan-2-one and mixtures thereof.

36. Chewing gum according to any of claims 1- 35,
30 wherein cyclic ester polymers and their copolymers resulting from the polymerization of cyclic ester monomers include, but are not limited to : poly (L-

lactide) ; poly (D-lactide) ; poly (D, L-lactide) ; poly (mesolactide) ; poly (glycolide)
; poly (trimethylenecarbonate) ; poly (epsilon-caprolactone) ;
poly (L-lactide-co-D, L-lactide) ; poly (L-lactide-co-meso-lactide) ; poly (L-lactide
co-glycolide) ; poly (L-lactide-co-trimethylenecarbonate) ; poly (L-lactide
5 co-epsilon-caprolactone) ; poly (D, L-lactide-co-meso-lactide) ; poly (D, L
lactide-co-glycolide) ; poly (D, L-lactide-co-trimethylenecarbonate) ;
poly (D, L-lactide-co-epsilon-caprolactone) ; poly (meso-lactide-co
glycolide) ; poly (meso-lactide-co-trimethylenecarbonate) ; poly (meso
lactide-co-epsilon-caprolactone) ; poly (glycolide-cotrimethylenecarbonate) ; poly
10 (glycolide-co-epsilon-caprolactone).

37. Chewing gum according to any of claims 1-36,
wherein the chewing gum comprises filler.
- 15 38. Chewing gum according to any of claims 1- 37,
wherein the chewing gum comprises filler in an amount of about 0 to about 50% by
weight of the chewing gum, more typically about 10 to about 40 % by weight of the
chewing gum.
- 20 39. Chewing gum according to any of claims 1-38,
wherein the chewing gum comprises at least one coloring agent..
40. Chewing gum according to any of claims 1-39, where the chewing gum is coated
with an outer coating.
- 25 41. Chewing gum according to any of claims 1-40, wherein the outer coating is a
hard coating.
42. Chewing gum according to any of claims 1-41, wherein the hard coating is a
30 coating selected from the group consisting of a sugar coating and a sugarless coating
and a combination thereof.

43. Chewing gum according to any of claims 1-42, wherein the hard coating comprises 50 to 100% by weight of a polyol selected from the group consisting of sorbitol, maltitol, mannitol, xylitol, erythritol, lactitol and isomalt.
- 5 44. Chewing gum according to any of claims 1-43, wherein the outer coating is an edible film comprising at least one component selected from the group consisting of an edible film-forming agent and a wax.
- 10 45. Chewing gum according to any of claims 1-44, wherein the film-forming agent is selected from the group consisting of a cellulose derivative, a modified starch, a dextrin, gelatine, shellac, gum arabic, zein, a vegetable gum, a synthetic polymer and any combination thereof.
- 15 46. Chewing gum according to any of claims 1-45, wherein the outer coating comprises at least one additive component selected from the group consisting of a binding agent, a moisture absorbing component, a film forming agent, a dispersing agent, an antisticking component, a bulking agent, a flavouring agent, a colouring agent, a pharmaceutically or cosmetically active component, a lipid component, a wax component, a sugar, an acid and an agent capable of accelerating the after-
20 chewing degradation of the degradable polymer.
47. Chewing gum according to any of claims 1-46, wherein the outer coating is a soft coating.
- 25 48. Chewing gum according to any of claims 1-47, wherein the soft coating comprises a sugar free coating agent.
49. Chewing gum according to any of claims 1-48,
wherein said chewing gum comprises conventional chewing gum polymers or resins.
- 30 50. Chewing gum according to any of claims 1-49,

wherein the at least one biodegradable polymer comprises at least 5% of the chewing gum polymers.

51. Chewing gum according to any of claims 1-50,
5 wherein all the biodegradable polymers comprised in the chewing gum comprises at least 25%, preferably at least 50% of the chewing gum polymers.

52. Chewing gum according to any of claims 1-51,
wherein all the biodegradable polymers comprised in the chewing gum comprises at
10 least 80%, preferably at least 90% of the chewing gum polymers.

53. Chewing gum according to any of claims 1-52,
wherein said chewing gum comprises
- said at least one biodegradable polyester copolymer forming a plasticizer of the
15 chewing gum and
- at least one non-biodegradable conventional elastomer.

54. Chewing gum according to any of claims 1-53,
wherein said chewing gum comprises
20 - said at least one biodegradable polyester copolymer forming an elastomer of the chewing gum and
- at least one non-biodegradable conventional natural or synthetic resin.

55. Chewing gum according to any of the claims 1-54, wherein said chewing gum
25 comprises

at least one biodegradable elastomer in the amount of about 0.5 to about 70% wt of the chewing gum,

30 at least one biodegradable plasticizer in the amount of about 0.5 to about 70% wt of the chewing gum and

at least one chewing gum ingredient chosen from the groups of softeners, sweeteners, flavoring agents, active ingredients and fillers in the amount of about 2 to about 80% wt of the chewing gum.

- 5 56. Gum base according to any of claims 1-55.

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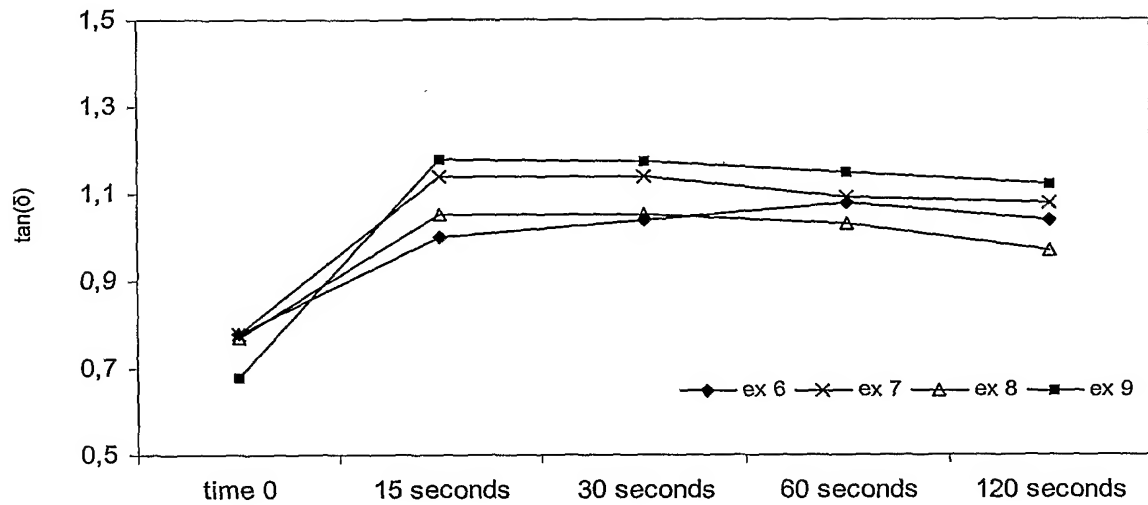


Fig. 1

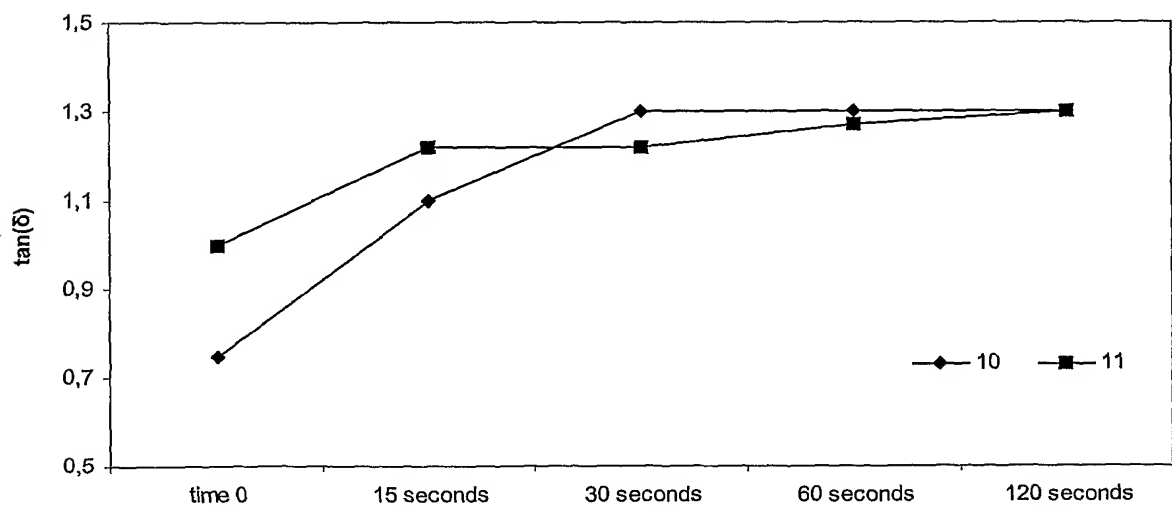


Fig. 2

INTERNATIONAL SEARCH REPORT

Inte XXXXXXXXXX Application No
PCT/DK 02/00624

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A23G3/30		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 A23G		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data, PAJ		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 711 506 A (UNIV GRONINGEN) 15 May 1996 (1996-05-15) column 1, line 27 - line 30 column 1, line 46 - line 50 column 2, line 4 - line 7 column 2, line 39 column 2, line 52 column 2, line 53 column 3, line 10 - line 11 column 3, line 20 - line 22; claims abstract	1-56
A	--- US 3 800 006 A (KATAYAMA S ET AL) 26 March 1974 (1974-03-26) the whole document -----	1-56
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex. </div>		
° Special categories of cited documents :		
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>		
Date of the actual completion of the international search <div style="text-align: center; font-weight: bold;">9 May 2003</div>		Date of mailing of the international search report <div style="text-align: center; font-weight: bold;">28. 05. 2003</div>
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer <div style="text-align: center; font-weight: bold;">DAGMAR JÄRVMAN / ELY</div>

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/DK 02/00624

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